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ABSTRACT

The Division of Applied Research of the National Institute on Drug Abuse sponsored a Consensus Conference at which key technical, scientific, and procedural issues of employee drug testing could be discussed. The conference, which included politicians and government officials; representatives of business, industry, and labor; and laboratory scientists and physicians, addressed four major subject areas related to testing guideline issues and three major areas of concern related to laboratory certification. The specific topics discussed, a synopsis of critiques developed from the proceedings, the consensus statements, and the recommendations to the Department of Health and Human Services (HHS) are included in this report. The report on scientific/technical guideline issues focuses on analytical methods, specimen collection and reporting results, additional drug and cut-off levels, and the role of the medical review officer. For each of these areas, specific issues are identified, a critique is given, and consensus statements are made. The report on laboratory certification issues examines performance testing, laboratory inspections, and monitoring laboratory performance. A glossary of terms, a list of working group members, a list of consensus conference participants, and the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are appended. (NB)

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Technical, Scientific
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Procedural Issues
of

Employee Drug Testing

Consensus Report

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

TECHNICAL, SCIENTIFIC AND PROCEDURAL ISSUES OF EMPLOYEE DRUG TESTING

Consensus Report

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HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

PREFACE

On September 15, 1986, President Reagan issued Executive Order (EO) #12564, which required all Federal agencies to develop programs and policies to achieve a drug-free Federal workplace. One of the requirements of the EO was that agencies institute employee drug testing under specified circumstances. The responsibility for developing technical and scientific guidelines for these drug testing programs was assigned to the Secretary of Health and Human Services (HHS) and delegated to the National Institute on Drug Abuse (NIDA).

On February 19, 1987, the Secretary (HHS), Dr. Otis Bowen, issued the required set of technical and scientific guidelines for Federal drug testing programs. As there was significant opposition to Federal employee drug testing in the Congress, legislation was proposed in the House of Representatives to prohibit the expenditure of "appropriated funds" to implement EO #12564. Several months of negotiation between the Administration and the Congress resulted in the passage of a new law (PL 100-71, sec. 503).

Enacted on July 7, 1987, this law permitted the President's program to go forward only if a number of administrative prerequisites were met. Included in the list of required administrative actions was that the Secretary (HHS) must publish the HHS technical and scientific guidelines in the Federal Register for notice and comment [for a period of not less than 60 days], and to expand the "Guidelines" to include standards for laboratory certification.

On August 13, 1987, the "Guidelines" were published in the Federal Register as required, and the comment period closed on October 13, 1987. Approximately 150 comments were received during this period, some of which were extremely detailed and lengthy. Several months were required to evaluate the advice received, make the appropriate revisions, and to fully develop the standards for laboratory certification. The revised "Guidelines" and "Lab Certification Standards" were cleared through HHS and the Office of Management and Budget, and were published in the Federal Register as the final "Mandatory Guidelines for Federal Workplace Drug Testing Programs", on April 11, 1988 (See Appendix D).

In July 1988, utilizing the certification standards, a National Laboratory Certification Program was implemented by HHS/NIDA, and since that time approximately 50 laboratories have been certified, with another 100 or more still in process.

During 1988-89, both the Department of Transportation and the Nuclear Regulatory Commission issued regulations which require employee drug testing in their regulated industries. Furthermore, these regulations require the use of a laboratory that has been certified by HHS/NIDA, and that these private sector organizations follow the technical and scientific procedures set out in the "Mandatory Guidelines" with minor exceptions.

In 1988, 1989, and again in 1990, legislation has been proposed in both the House and the Senate, which would impose Federal standards for drug testing in the private sector. Congressmen Dingle (D-MI) and Bliley (R-VA) have introduced HR33 which would require the Secretary HHS to establish a Federal standard for test procedures and require the use of certified laboratories for all employee drug testing conducted in the United States. Similar legislation has been introduced in the Senate by Senators Hatch (R-UT) and Boren (D-OK). In January 1990, a House version of the Hatch/Boren bill was introduced as HR3940.

There appears to be general support for the concept of a single Federal standard for all employee drug testing. Business is supportive of a preemptive Federal statute that would eliminate the various state laws that have been enacted within the last 2-3 years. Since these state statutes vary considerably, businesses that have multistate operations must have a different policy for each state in which they operate. Business and industry appear ready to support Federal legislation, if such legislation will allow sufficient flexibility to employers. Labor is supportive of Federal legislation that would provide protections for employees, guarantee due process, and state required procedural standards for collection and analysis of specimens. At this juncture, it seems reasonable to believe that if consensus can be achieved on the details of procedures and analysis, a single Federal standard could be developed to apply to all employee drug testing.

INTRODUCTION

As authorized by Executive Order 12564 and PL 100-71, the Department of Health and Human Services (HHS), has issued "Mandatory Guidelines for Federal Workplace Drug Testing Programs". These "mandatory guidelines" established federal standards for conducting urine drug testing on Federal employees, and certification standards for laboratories which would test these specimens. The institution of these standards, together with the National Laboratory Certification Program, was novel for clinical chemists and toxicologists. It established a precedent and sound basis requiring good laboratory practices in conducting employee drug testing in cases which must withstand legal scrutiny. It was difficult and stressful for those laboratory scientists involved at the outset. The decade of the 80s manifested a remarkable sequence of events driven by a serious determination to address drug abuse problems in the workplace. Early on, there was clear recognition that accurate, reliable, and precise laboratory analysis of appropriate body fluid specimens would be the key to deterrence, the early detection of drug use, and employee assistance, treatment, and rehabilitation programs.

Scientists from NIDA, together with forensic toxicologists worked steadily to define a practical laboratory program, expanding, constricting, defining, refining, and finally culminating in a paradigm which permits testing of human urine for five commonly abused drugs, with a minimum of error and a maximum of protection for individual employees. No single event, individual, discovery, or discipline can be identified as the sole contributor to this accomplishment; rather, a combination of technological advances and management techniques were applied in the context of forensic science to a rapidly expanding drug abuse problem of urgent concern to society.

A great benefit of the development and implementation of the "guidelines", and the laboratory certification program is that they have illuminated the process by which drugs and metabolites are analyzed (in body fluids) with such brilliance and in such detail that they focus the attention of analysts, lawyers, politicians, and many lay persons on those aspects of non-medical drug testing which are essential to forensic credibility. The concepts of chain-of-custody, security, the use of validated methods, quality control/assurance, purity of reference standards, qualified personnel, record keeping and other factors beyond the actual analytical method itself are elucidated, all of which have long been of concern to the forensic scientist. Now, after some reluctance, non-forensic analysts have learned the value of these concepts not only to meet certification standards, but because their clients are demanding this standard of practice.

It is difficult to convey the magnitude of the changes in the approach to forensic drug testing that have occurred in the last three years. They have truly revolutionized laboratory practices. However, despite all efforts to ensure the best possible program, the proof of any plan is in the execution, and it is never perfect. The current NIDA guidelines are not perfect, nor should they be considered immutable. As experience in their application has been gained, it is recognized that improvements are needed to respond to practical considerations, technological advances, and the goal of effectively identifying drug use. A number of operational issues have been raised which require resolution; particularly at a time when federally mandated testing is rapidly expanding beyond the Federal workplace into the private sector. The government, and HHS/NIDA in particular, urgently need the opinions of the professionals who are involved in all aspects of this program, and after 18 months of operations, it seems appropriate to assess and evaluate whether the program is maturing rationally and concurrently with identified practical concerns. In addition, the pending legislation that would require HHS to set Federal requirements for all private sector testing demands that HHS assess the needs and capabilities of private sector employers and their workers.

To achieve this assessment and develop recommendations for change, NIDA's Division of Applied Research sponsored a Consensus Conference at which key technical, scientific, and procedural issues of employee drug testing could be discussed. The conference brought together a diverse group of interested parties including: politicians and government officials, representatives of business, industry and labor, as well as laboratory scientists and physicians. Four major subject areas related to testing guideline issues, and three major subject areas of concern related to laboratory certification were discussed in both working groups and in plenary sessions. All participants, therefore, contributed to the consensus opinions of the conference, but the working groups and the group leaders were responsible for reducing the issues, discussion, and conflicting opinions to a coherent, balanced, consensus statement [where possible]. The specific topics discussed, a synopsis of the critiques developed from the proceedings, the consensus statements and the recommendations to HHS have been synthesized into the report that follows.

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N.B. We discovered in editing this document that a number of terms were used interchangeably by the working groups. In order to provide uniformity of terminology, a glossary of terms was developed (See Appendix A) and those defined terms are used throughout.

ACKNOWLEDGMENTS

The logistics for conducting a consensus meeting where all attendees were provided the opportunity to be integrally involved in a working process of developing consensus statements required the assistance of many individuals. The editors would like to express sincere appreciation to the seven workgroup chairmen (Dr. Michael Peat, Mr. Jay Whitney, Dr. Alan Jones, Dr. Douglas Rollins, Dr. Thorne Butler, Dr. Alphonse Poklis, and Dr. Yale Caplan) for their diligence in assembling working groups that truly represented all interested parties, their diplomacy in mediating the sometimes heated discussions on the many difficult issues, and their perseverance in moving the groups toward consensus. Much appreciation is also due to the members of the working groups (See Appendix B) who brought their knowledge and expertise to the table to insure that all sides of the issues were considered. And finally, the participants of this meeting deserve special recognition. We knew that the level of interest in the issues was keen, and we knew that the attendees wished to be involved in the consensus process, but we were truly impressed by the level of commitment made by the very special group of participants who attended this meeting (See Appendix C). These individuals not only attended the 8:30 a.m. to 5:00 p.m. scheduled activities but actively participated in the marathon workgroup sessions which lasted past midnight for two nights of the three day meeting. Their personal commitment and involvement in the process forced the working groups to address some very difficult issues that otherwise would have been avoided.

EXECUTIVE SUMMARY
OF GENERAL RECOMMENDATIONS

The seven working groups, with significant assistance from the general audience participants, were able to reach consensus and make many recommendations for the improvement of the present NIDA Guidelines. All of these consensus statements are presented in detail together with their rationale in the following chapters of this report. This section presents some of the salient recommendations only.

A. There were some issues which were considered by multiple working groups; these included on-site testing, additional drugs, cut-off (analytical threshold) values, and laboratory inspections. It is interesting that the separate groups expressed very similar opinions on these issues and their independent assessments lend weight to their collective consensus recommendations.

ON-SITE, INITIAL SCREENING-ONLY TESTING FACILITIES

- These facilities should only be allowed where safety issues demand the most rapid turnaround time, justifying the risks to the client inherent in unconfirmed test results and the considerable difficulties in achieving accurate testing that such facilities create.

- On-site urine screening can reliably identify negative specimens provided appropriate safeguards are built into the procedure. These precautions include:

  - meeting the basic forensic standards for specimen collection, chain-of-custody documentation, and security.
  - splitting the collected urine specimen into two portions.
  - participation in open and blind proficiency testing.
  - a rigorous quality assurance program.
  - being subject to site inspections.
  - using an FDA approved screening test that provides objective and documentable results.
  - use of the same cut-off concentrations as used in NIDA certified laboratories.
  - submitting all presumptive positive specimens to a NIDA certified laboratory for confirmation.

- If laboratory testing is performed on-site, all MRO functions should remain the same as at present. Other recommendations associated with this issue are given in the body of the report.

ADDITIONAL DRUGS

- Additional drugs should be considered for inclusion in urine testing protocols when they can be justified as special problems in particular workplace environments.

- Drugs that might be considered include the benzodiazepines, barbiturates, and other selected psychoactive agents.

- The option to include additional drugs should be decided by the employer but all testing must be at a NIDA certified laboratory, and the criteria for the analytical methods and laboratory procedures must meet the present NIDA Guidelines in every respect.

CUT-OFF (ANALYTICAL THRESHOLD) VALUES

- Any immunoassay should have an assay specific threshold concentration based on agreement with a GC-MS reference method.

- The present cut-off levels should be reviewed and possibly revised based on operational data to date, but any changes must meet program administrative needs and protect the employee from any possibility of false positive results.

- The screening cut-off value for cannabinoids (delta-9-THC-acid) could be reduced from 100ng/ml to 50ng/ml; the confirmation cut-off remaining at 15ng/ml.

- The present screening cut-off value for cocaine (benzoylecognine) could be reduced to 200ng/ml and the confirmation to 100ng/ml.

LABORATORY INSPECTIONS AND CERTIFICATION

- Beginning from the time of certification, inspection should occur at 6, 12, 18, and 24 months; following these two years, inspections should occur annually.

- A minimum of three inspectors should participate in the initial inspection, before certification of a laboratory, and then a minimum of two inspectors for routine, maintenance inspections after certification.

- Inspectors should be carefully selected and trained to meet the same standards, and training programs should stress the critical need for inspection criteria to be applied uniformly, without bias.

- An exit summation conference between the inspection team and the person responsible for the laboratory operations should present any deficiencies and other identified problems. At the conference the laboratory person should have the opportunity to clarify misunderstandings.

- Supportive analytical data from the prior 60 days should be readily available for inspectors to review.

- The cost of laboratory inspections should be reduced to a reasonable level and reflect the shortened time, and fewer inspectors necessary for small laboratories.

- The Department of Health and Human Services (HHS) should have an oversight function to monitor certification agencies, and the Secretary of HHS should rapidly establish methods to grant equivalency to acceptable certifying agencies.

- Laboratories seeking certification should be subject to the same standards even though they may be monitored by different certification agencies.

There was only one issue on which consensus proved impossible; that was whether the Medical Review Officer (MRO) should continue to receive, review and release all positive ***and negative*** drug test results. Both the MRO and the Specimen Collection working groups discussed this issue intensely, separately and together. It was agreed that positive results should be released by the MRO as soon as possible but no consensus was reached on whether MROs should continue to receive and review all negative drug tests as at present. Serious concerns were raised about confidentiality issues caused by direct transmission of results to an employer rather than sending them to the MRO. Several alternative compromise procedures were acceptable to the Specimen Collection working group but not to the MROs. ***Consensus could not*** therefore be achieved.

B. The following represents an Executive Summary of the principal recommendations on issues considered by the individual working groups. However, for complete consensus statements the appropriate section in the body of the report should be read.

ANALYTICAL METHODS

- Initial screening and confirmation methods must be based on different principles of analytical chemistry or different chromatographic separations.

- Laboratories should be allowed to establish their own analytical procedures, but they must provide statistical validation and meet all of the criteria required of the present immunoassay screening methods and GC-MS confirmation procedures.

- Urine continues to be the best specimen for analysis in the context of detecting drug use in the workplace. There are insufficient data to support a recommendation for alternative specimens such as hair or saliva.

SPECIMEN COLLECTION AND REPORTING RESULTS

- A urine volume of 30ml should be an acceptable specimen volume, provided that it does not create any technical problems for the laboratory.

- Split urine specimens should be permitted provided they are both part of the same specimen and handled with identical safeguards.

- Testing urine specimens at the collection site for acceptable pH, specific gravity and creatinine values should be permitted but not required, at the option of the employer. The temperature measurement requirement should be maintained, the acceptable range should be 90° - 100° F.

- Negative results should be reported to the employer promptly by direct means, but in a manner which ensures confidentiality of the information.

THE ROLE OF THE MEDICAL REVIEW OFFICER (MRO)

- MROs should be licensed doctors of medicine or osteopathy.

- A comprehensive continuing education program that addresses all aspects of MRO functions (not just drug abuse recognition) should be developed.

- Guidelines should be developed to define confidentiality when any new high technology electronic transmitting equipment is used in a urine drug testing program.

- Action should be taken in a drug deterrence program only after a specimen is confirmed positive and verified to be a true positive by the MRO.

- In unusual circumstances MROs should be able to request, in consultation with a laboratory director, additional tests on positive specimens that may aid in a complete identification of the drug, metabolite, or of the specimen.

PERFORMANCE TESTING

- Proficiency testing (PT) is necessary to establish laboratory performance before as well as after certification.

- Blind proficiency testing is the ultimate method for demonstrating the competence of a laboratory since it tests the entire laboratory operation as applied to routine specimens.

- The specific analytes and their concentrations in the PT specimens must be prepared and verified by an independent agency unknown to the laboratory.

- Urine used for the preparation of PT specimens should be human, drug-free urine.

- For all PT challenges a false positive result shall be cause for disqualification from certification.

- For all PT challenges the concentration for each analyte should be determined from the mean of the results obtained from the reference laboratories' analyses.

- In the initial PT series before certification, quantitative results may differ by no more than 50% from the target value. If one result differs by more than this amount, the laboratory should demonstrate that appropriate remedial action was taken and successfully complete an additional PT cycle of 20 specimens. After achieving certification a laboratory is permitted one quantitative result differing by more than 50% from the target value within three consecutive cycles of PT.

- Methods of keeping costs to the client at a minimum while maintaining maximum proficiency monitoring should be investigated. A centralized, blind PT program may serve this purpose, but details of such a program would need to be carefully defined.

MONITORING LABORATORY PERFORMANCE (AFTER CERTIFICATION)

- A single agency should monitor the performance of all laboratories certified for urine drug testing. The agency should be supported by an advisory group representing all appropriate, involved professionals, meeting frequently at regularly scheduled intervals to provide policy advice and problem review.

- The monitoring agency should return a report which summarizes the laboratory performance as compared to the group mean result, within 30 calendar days following receipt of the laboratory performance test results.

- A uniform set of specifications for blind PT specimens should be developed. These would include a mechanism for submitting the specimens and receiving/evaluating reports of blind PT results. These specimens should be introduced proportionally over time to include a minimum of 3% of the number of client specimens.

- A variety of communication systems, such as a newsletter, electronic bulletin boards, regularly scheduled meetings of representatives of certified laboratories and the monitoring agency, should be explored and developed in order to share information of importance in urine drug testing.

- Detection of an apparent false positive test result is of such importance that immediate action should be initiated to investigate the cause. The investigation should be completed by the laboratory within seven calendar days of receipt of notice.

- When certification of a laboratory is suspended, the laboratory should immediately notify all clients of the suspension; failure to do so should result in revocation of certification. If revocation occurs then the entire initial certification process should be completed before further testing is resumed.

- The monitoring agency should publish an updated list of certified laboratories monthly.

Those laboratories which conform to the NIDA Guidelines and are certified as competent continue to demonstrate that test results which are credible in the forensic context can be produced routinely on very large numbers of urine specimens. The experience of the past two years has made it abundantly clear that almost all of the demands which are made on the analytical process and administrative system which supports urine drug testing in the workplace can be quickly satisfied by thoughtful, imaginative scientists and managers. Automated immunoassays can reliably discriminate between negative and potentially positive specimens. Microprocessor or computer controlled GC-MS instruments can specifically confirm structures, resolve isomers and quantitate drugs and metabolite concentrations at parts per billion and smaller with remarkable accuracy. Conscientious application of a rigorous quality assurance program and management dedicated to the principles of fail-safe practices can insure success in detecting and deterring drug use in the workplace.

REPORT ON SCIENTIFIC/TECHNICAL GUIDELINE ISSUES

1. ANALYTICAL METHODS

1.1 Specific Issues

- Should laboratories be allowed to establish their own initial (screening) test procedures?
- Are current cut-off concentrations for initial test procedures appropriate?
- Is on-site initial screening feasible?
- Are mass spectrometric (MS) methods the only acceptable analytical procedures for confirming initial test results?
- Is quantitative gas chromatography-mass spectrometry (GC-MS) necessary?
- Are test specimens other than urine useful for testing?
- Is there a need for certified reference materials?

1.2 Critique

The approach to screening for abused drugs embodied in the current Federal guidelines for laboratories permits rapid identification of presumptively positive urine specimens within a framework of extensive and uniform quality control. The specifications in the guidelines for screening methods and threshold (cut-off) concentrations have provided an appropriate choice for screening large numbers of urine specimens, given available technologies. However, these methods are limited to various immunoassay techniques and there are good arguments for permitting other well-established methods such as thin-layer chromatography or high performance liquid chromatography if they can satisfy the acceptance, performance criteria presently defined for immunoassays. Such methods might be of benefit to small laboratories and those which perform limited numbers of analyses. In addition, when other drugs are considered, the availability of immunoassays may be limited.

Methods cannot and must not be changed whimsically, without careful evaluation and regard to their effects on particular programs. In addition to meeting legal and scientific requirements, implementation of any alternative screening method must be accompanied by dissemination of appropriate information to employers and employees, so that those subject to the requirements of a urine drug testing program do not perceive any diminution of safeguards in the testing process.

For immunoassays, it is important to define carefully their differing specificities, and the use of a single threshold concentration for a given analyte may not be appropriate. A single threshold value does not take into consideration that the differences in cross reactivity of a given assay may give a different, although consistent, result with another assay. It becomes very important that the determination of any immunoassay threshold value be based upon agreement with a fixed reference method, such as gas chromatography-mass spectrometry (GC-MS). This would provide a more consistent determination of positives and negatives. The same rationale should apply to other, non-immunoassay methods which may be used for initial screening of samples.

Given the broad range of qualitative screening methods available, it is reasonable that laboratory scientists should be allowed to establish their own procedures. If they choose to do so, these must be reproducible, objective, and have specifically designated cut-off concentrations. A laboratory which develops its own initial test procedure or the commercial manufacturer of that procedure should establish the cut-off concentration based upon a comparison with the threshold values of their mass spectrometric confirmation method. This comparison and establishment of the initial test cut-off concentration must be based on accepted statistical procedures using real specimens, not fortified urine samples. Validation should be documented by the laboratory or the manufacturer, but the cut-off concentration cannot be higher than the values indicated in the NIDA Guidelines. Any laboratory which establishes a new procedure must satisfy all of the blind and open performance testing requirements.

The present requirement that the initial and confirmatory test procedures should be different, that is, based on different chemical principles or chromatographic separations is well-founded in good laboratory practices and provides an important additional level of assurance that the results are correct. GC-MS is capable of providing accurate, qualitative, specific identification of drugs and metabolites at very low concentrations (ng/ml and less) as well as accurate quantitative results. At present there does not seem to be any other technique which can match its suitability as a confirmation reference method. The linearity of the method around the threshold concentration must be established and documented. Analysts however, should not become dogmatic and closed-minded, and they should remain alert to new developments that could provide alternative methods in the future.

It is perhaps desirable to consider alternative specimens for analysis. Although not strictly invasive, collection of urine (see Specimen Collection) is not without difficulties, and it has been reported in the scientific and medical literature for many years that certain drugs of abuse can be detected in hair and saliva. Blood is undoubtedly the most appropriate sample for some applications, but the invasive sampling technique makes it unsuitable for use in mass screening.

Saliva, a biological fluid generally collected from the parotid gland in the mouth has perhaps even more difficulties and variables than a urine specimen, and, therefore, may not provide any advantage other than convenience of collection. The biodisposition and kinetics of abused drugs in saliva are not well understood and therefore interpretation of analytical data cannot be made reliably. Recent research reports on the analysis of hair have clearly indicated that there is a great deal yet to be learned about the pharmacokinetics of drugs in hair and the adequacy of hair as a specimen for drug and metabolite analysis. Drugs of abuse and their metabolites can be detected in hair but studies have raised many questions about the nature and specification of the hair sample, the dispositional kinetics and reproducibility of results from hair analysis. It is, therefore, too soon to adopt these alternative specimens because there is clearly insufficient, established data available, at present, for their use in mass screening.

For any analytical method accuracy, precision and sensitivity, that is, the statistical base which establishes the method, relies upon certified reference material. With the exception of the delta-9-carboxylic acid metabolite of delta-9-THC no such materials exist at present for abused drug analysis in urine samples. This is a critical issue which needs to be addressed if present methods are to be adequately defined and, particularly, if new alternate procedures are to be introduced.

The working group recognized that on-site screening may be appropriate in certain situations, and were of the opinion that on-site screening, with clearly defined safeguards, could reliably identify negative specimens. There are, however, several important caveats. The probability that the result of a test is correct is dependent upon a number of factors, including the specificity and sensitivity of the assay used. The frequency of "false positive" and "false negative" results detected on-site is likely to be greater than that from a certified laboratory. This is because there is a lower probability of a result from a procedure which relies on a single test being correct compared to one requiring two methods based on different chemical principles, such as immunoassay and gas chromatography-mass spectrometry.

The determination of those situations in which on-site screening may be appropriate is a policy rather a scientific decision, and must balance the recognition of the potential for greater error with the need for rapid results. On-site screening could be performed at either the collection site or in a separate facility nearby. Obviously, if this separate facility performs both screening and confirmation, it should be considered as a laboratory subject to NIDA certification requirements.

1.3 Consensus Statements

- General: Initial screening and confirmatory methods must be based on different chemical principles or different chromatographic separations.

- Laboratories should be allowed to establish their own procedures, but they must provide statistical validation and meet all of the criteria required of the present immunoassay screening methods and GC-MS confirmation procedures.

- Any immunoassay should have an assay specific threshold concentration (cut-off) based on agreement with a GC-MS reference method.

- Mass spectrometric method coupled with a chromatographic separation is currently the only suitable confirmatory procedure.

- Urine continues to be the best specimen for analysis in the context of detecting drug use in the workplace. There are insufficient data to support a recommendation for alternative specimens such as hair or saliva.

- National Institute for Science and Technology (U.S. Department of Commerce), private organizations or both should be encouraged and funded by agencies such as NIDA to accelerate the development of a urine based reference material for abused drug analysis. This material must be suitable for both screening and confirmation methods.

- <u>On-Site Screening:</u> On-site screening can reliably identify negative specimens provided appropriate safeguards are built into the procedure. These safeguards include:

  - A rigorous quality assurance program including the analysis of performance testing samples.
  - Security of the facility to preserve the integrity of the specimens.
  - Chain of custody documentation.
  - Availability of trained personnel to perform the tests and document results.
  - Use of an FDA approved screening test that provides objective and documentable results.
  - Use of the same cut-off concentration as used in certified laboratories.
  - Retention of all records relating to the screening procedure, including chain-of-custody documentation, quality control results and results on all specimens analyzed.
  - Forwarding under chain of custody of all "presumptive positive" specimens to a certified laboratory for testing by their screening and confirmatory test procedures.

The working group also strongly recommended that a percentage of the specimens that screened negative be sent to a certified laboratory for testing. A review of these data would allow an oversight inspection team to determine the incidence of false negatives.

2. SPECIMEN COLLECTION AND REPORTING RESULTS

2.1 Specific Issues

- Is the present collection procedure appropriate?
- What is the optimal volume of urine required?
- Are observation and same gender collector necessary?
- Are current record-keeping forms and procedures appropriate?
- What are the criteria for an acceptable specimen?
- Do current procedures for reporting results require modification?

2.2 Critique

The specimen is considered to be the total volume of urine collected and supplied to the laboratory, and any aliquot or portion taken from it. The specimen particularly, and aliquots taken from it, constitute the physical evidence upon which analytical procedures are used to produce information to decide whether drug use has occurred. A decision that drug use has occurred can be challenged; it must be defendable in a legal setting and, therefore, specimen management is a critical issue. Inadequacies in the specimen which are a result of mismanagement, can negate or reverse any decision made from the testing procedure. Management problems are the most common and most successfully challenged deficiencies in forensic urine drug testing. They include misidentification of the specimen, non-identification, contamination, substitution, adulteration, and loss. It is the responsibility of the laboratory to maintain an audit trail for the specimen which includes external and internal chains-of-custody, and security at the laboratory characterized by restricted, authorized access, and documentation of access. At present, specimen collection procedures often follow instructions from the laboratory which may include collection vessels as part of a kit and instructions for transportation.

All drug testing specimens are potentially legal evidence. Their management must include recognized forensic procedures, and is a shared responsibility of staff at the collection site and the laboratory. The current requirement for collection of a minimum of 60ml of urine has led to some difficulties in a substantial number of cases in which the donor is required to wait and provide additional urine, so that the final specimen becomes accumulated volumes collected intermittently. Consideration should,

therefore, be given to collecting a smaller volume which is still adequate for the laboratory and program needs. This would eliminate the practice of collecting and combining partial specimens. Many employers in the private sector have binding agreements with labor which require split specimens (see glossary), but this is not covered in the present NIDA Guidelines. Split specimens do not compromise the drug testing program provided both samples are handled with identical security, confidentiality, and chain-of-custody safeguards. If the volume and quality of the specimen collected is appropriate then analyses for additional drugs could be made on the same specimen used for the currently authorized drugs.

The NIDA Guidelines require, in certain circumstances, that specimens be obtained under the direct observation of a collection site person of the same gender as the employee, and also require a higher level supervisor to review and agree in advance with a decision to obtain the specimen under direct observation. This sometimes presents personael difficulties for those involved, and the working group considered carefully the necessity for this requirement. It might facilitate matters, without loss of specimen validation, if the collection site staff person was permitted to use a same gender "witness" to obtain the specimen under direct observation, but only allowed after obtaining appropriate authorization from the appropriate senior individual within the agency (employer).

Specimen acceptance criteria such as pH, specific gravity and creatinine values are performed at the laboratory and the specimen accepted or rejected according to the results. Officially, NIDA procedures do not permit examination of the specimen in this manner at the collection site. The specimen can be physically examined and the temperature of the urine measured at collection but it is possible that some employers would find testing pH, specific gravity and creatinine useful, particularly as a deterrent to specimen adulteration. Such testing at the collection site, however, is dependent on the availability of convenient and accurate test methods.

Adequate record-keeping at the collection site is very important and involves at least fully completed chain-of-custody forms or a separate bound log-book in which identifying data on each specimen collected at the site are permanently recorded in the sequence of collection. The NIDA Guidelines are not clear and precise on this issue but these are the records which initiate the legal chain-of-custody for each and every specimen. [1] When analytical results are reported, they are in a batch consisting of all specimens submitted at the same time to the laboratory. Reporting both positive and negative results awaits completion of the

[1] A new chain-of-custody form is now available which eliminates the requirement for a permanent record book.

batch. It is thought that this delays, unnecessarily, reporting of negative results. Although there is no apparent evidence of prejudicial treatment based on the time required to receive completed test results, obviously those which test negative are known significantly earlier than the positive results. Confidential, direct transmission of negative results to the employer by secure teleprinters, facsimile or computers, might significantly alleviate this problem. This would mean that the Medical Review Officer would not receive all results, and this caused considerable debate between the MRO and the Specimen Collection working groups. At present, the actual review of negative results by the MRO is permitted but is not a requirement in the NIDA Guidelines. Serious concerns were raised however, about confidentiality issues caused by direct transmission of all results to an employer rather than sending them to the MRO. Several alternative compromise procedures were acceptable to the Specimen Collection working group but not to the Medical Review Officers. Consensus could not therefore be reached.

2.3 Consensus Statements

- A urine volume of 30ml should be an acceptable specimen volume, provided that it does not create any technical problems for the laboratory.

- Split urine specimens should be permitted provided they are both part of the same specimen and are handled with identical safeguards.

- In the event that additional drugs are authorized for testing, then analysis should be on the same specimen used to determine currently authorized drugs.

- Testing urine specimens at the collection site for acceptable pH, specific gravity and creatinine values should be permitted but not required, at the option of the employer. The temperature measurement requirement should be maintained, the acceptable range should be 90° - 100° F.

- When necessary, the collection site staff person should be permitted to use a same gender "witness" to obtain a urine specimen under direct observation but only after obtaining authorization from the appropriate senior individual in the agency. The "witness" as well as the collection site staff person must sign the chain-of-custody form.

- **The requirement that the analytical results for all specimens submitted at the same time to the laboratory shall be reported back at the same time should be deleted. The NIDA Guidelines should be revised to make it clear that review of negative results by Medical Review Officers is permitted but is not a requirement.**

- **Negative results should be reported to the employer promptly by direct means, but in a manner designed to ensure confidentiality of the information.**

- **Specimen collection should be performed in accordance with a set of detailed written procedures which are available at the collection site at all times.**

3. ADDITIONAL DRUG AND CUT-OFF LEVELS

3.1 Specific Issues

- Is there a need for threshold, cut-off concentrations for urine drug testing protocols?
- Should cut-off concentrations for different drugs and assays be uniform?
- Are present cut-off values for each drug and metabolite appropriate?
- Should additional drugs be included in the present analytical protocols?
- Is it feasible to add other drugs, and what are the requirements for doing so?

3.2 Critique

It is well-recognized that many other drugs in addition to the five which are tested under the present NIDA Guidelines, are misused or abused. Some of the drugs are known to impair behavior and this might well occur in the workplace. The most common and of greatest consequence is ethyl alcohol, but others including: the benzodiazepine sedative and anti-anxiety drugs, barbiturates, and some antihistamines which have sedative properties, methaqualone, methadone, and illicit drugs, new (MDMA and other substituted amphetamines) and old (LSD) are readily available. It can also be argued that tobacco (nicotine) and caffeine, particularly in withdrawal, cause behavioral changes that can be seriously detrimental. The illicit drugs such as the substituted amphetamines and LSD are not problems in all parts of the country, and there is little evidence that they are widely used by the employed population.

In contrast, the legal prescription and nonprescription drugs noted are widely used and many of them are potent pharmacological agents. Their inclusion in drug testing protocols would raise many ethical issues of confidentiality, employer and employee rights, and the likely involvement of physicians who treat these employees as patients. In addition to the social and legal complexities, additional drugs to be tested would necessitate major changes in analytical protocols, would require considerable work to develop and validate new assays, and would add major costs to testing programs which are already very expensive. Alcohol has long been known as a drug in the workplace and many companies and federal agencies have the means for identifying and assisting problem

drinkers in their workforce. Alcohol is, therefore, in a sense a separate issue which is managed by other well-established means. Nevertheless, in some special workplace settings such as in transportation or other defined high-risk occupations, it might well be justified to include some additional drugs, particularly selected sedatives.

The option to request analysis for additional drugs could reside with the employer provided all necessary safeguards for the employee are taken and validated laboratory procedures are in place. Employer's requests to test for any drug within the context of workplace safety is obviously not justified, practical or worthwhile.

Every analytical procedure has a cut-off or threshold concentration associated with it, that being the limit of detection or the limit of quantification. Establishing cut-off values is, therefore, a necessary part of the definition of any analytical method and cannot be avoided. Determination of statistical accuracy and precision of the method for each drug and metabolite at or about the cut-off concentration is required by existing NIDA Guidelines, and is appropriate. Threshold concentrations have additional utility; they provide safeguards to the employee because they define a positive or negative result well within the ultimate capability of the analytical method, and, therefore, help reduce false results to a minimum. Over time, the cut-off concentrations of various analytical methods have been reduced as the methods have been improved and refined. The levels should not be regarded as immutable, and as existing methods are improved and new techniques become available, threshold levels should be redefined, but always with the conservative approach that the risk of a false positive result must be eliminated. There are sufficient data for some of the present drugs, and the analytical methods used to detect them, to support reducing the cut-off concentrations, perhaps for the metabolites of THC (marijuana) and cocaine. In contrast, although present cut-off values for amphetamine(s) are apparently high, there are insufficient data to support a significant reduction for this group of drugs. Undoubtedly, some employees who have used drugs escape detection because of the cut-off levels, but the overriding consideration of avoiding indictment of an innocent employee must remain paramount.

3.3 Consensus Statements

- Additional drugs should be considered for inclusion in urine testing protocols when they can be justified as special problems in particular workplace environments.
- Drugs that might be considered included the benzodiazepines, barbiturates, and other selected psychoactive agents.
- The option to include additional drugs should be decided

by the employer, but all testing must be at a NIDA certified laboratory, and the criteria for the analytical methods and laboratory procedures must meet the present Guidelines with respect to an initial screening method and independent confirmatory test.

- For each candidate drug, screening and confirmation cut-off concentrations remain to be determined. These levels should be national in their application, as for the present HHS cited drugs.

- PT, open and blind QC programs must be in place for each additional drug before any testing of employee urine samples is undertaken. Laboratory performance on any additional drugs should be subject to NIDA inspection when the laboratory is inspected under the present program.

- Screening and confirmation cut-off values are justified for all analytical procedures, and, whenever possible, should be uniform for each assay and drug.

- The cut-off levels for the present 5 drugs should be reviewed and possibly revised based on operational experience to date.

- Any cut-off value should be supported by accuracy and precision data at or around the cut-off concentration, but should also meet administrative needs and protect the employee from any possibility of false positive results.

3.3.1 Recommended Revised Cut-Off Values

- Cannabinoids (delta-9-THC-acid) - reduce the screening cut-off from 100ng/ml to 50ng/ml; the confirmation cut-off level should remain unchanged at 15ng/ml. Cocaine (benzoylecgonine) - reduce the present screening cut-off level to 200 ng/ml and the confirmation level to 100 ng/ml. No changes are recommended for the opiates and phencyclidine.

- For the amphetamine(s) a study should be undertaken to critically evaluate present data for the purpose of recommending lower cut-off levels for both screening and confirmation. Laboratories should be able to resolve the d- and l-isomers of methamphetamine and amphetamine.

- All of the present cut-off levels should be retained until a careful laboratory evaluation of the recommended changes has been completed.

4. THE ROLE OF THE MEDICAL REVIEW OFFICER (MRO)

4.1 Specific Issues

- What are the appropriate professional qualifications and training requirements?
- What are the MRO's responsibilities concerning laboratory results?
- What should the MRO's professional relationship be with employers and employees?
- Should MROs review on-site testing results?
- What issues for the MRO are raised by the addition of other drugs and tests?

4.2 Critique

The Medical Review Officer is an integral part of any employee drug testing program based on concerns for health and safety in the workplace and for drug deterrence. The MRO assesses and determines whether an alternate medical explanation can account for a drug test result. Additional important functions of the MRO are to review fairness and credibility of test results and provide for the privacy and confidentiality of the employee's personal medical history during the course of reviewing drug test results. Clearly, an MRO must be a licensed doctor of medicine or osteopathy, and have a strong professional interest and experience in drug abuse programs, and in the role of urine testing as a part of these programs. The MRO is the lynch-pin between the client and laboratory, and therefore carries a responsibility which requires diplomacy, understanding technical and social issues, and being able to insure that all aspects of a urine test result are valid. The MRO may find it necessary to delegate authority with regard to his or her functions from time to time, but ultimate responsibility for determination of negative, positive, and non-contact positive results, remains that of the Medical Review Officer.

The MRO receives, reviews, and releases positive and negative drug test results. It is a matter of some concern that significant time and costs are involved in the review of negative drug tests and the issue of whether this function could be delegated or is a necessary part of MRO responsibilities is deserving of discussion. The MRO, however, must make a diligent attempt to contact any employee with a positive test result. When this is not possible within a reasonable time the MRO contacts the employer to

request assistance in finding the employee. If this is unsuccessful, the MRO reports the result to the employer as a "non-contact positive." The employer is then free to follow administrative procedures to deal with the employee. A method of secure electronic transmission of results from the laboratory to the MRO would be of considerable assistance in improving MRO responsiveness to employers.

Medical Review Officers may request quantitation of any confirmed positive urine specimen or re-analysis if they deem it necessary. The issue of urine tampering is handled, at present, in three different ways; specimens determined to be adulterated at the collection site require a second urine collection, specimens not conforming to pH limits are dealt with at the laboratory, and specimens not conforming to creatinine or specific gravity limits, or both, are handled by the MRO.

The major issue for Medical Review Officers continues to be employee confidentiality, particularly regarding the identification of drug-positive employees in safety-sensitive positions. A working definition of a safety-sensitive position would be helpful, but has not been made a part of present programs. Although the present urine drug testing program is designed as a deterrent program, policies at particular companies may dictate the necessity of a "fitness for duty" program, and urine drug testing plays a part in these programs. MROs have a professional role in these programs and have to take into account the different purpose and perspectives. However, it is not the responsibility, of the MRO to determine drug dependence or nondependence. Generally, where an employee assistance program (EAP) exists, the MRO, with due diligence, refers drug-positive employees to that program for further assessment and evaluation. If an EAP does not exist, the MRO is responsible for referring the employee to a community based substance abuse assessment program. Similarly, the MRO does not usually determine if an employee may return to work after participation in a drug substance abuse assessment program; however, MROs may elect to perform this function if it is within their area of professional competence. If any form of on-site testing occurs then the same rationale which support MRO functions in the present laboratory based program will dictate the necessity for equivalent MRO functions even though the laboratory is on-site, that is, at the employee's place of work.

4.3 Consensus Statements

- Medical Review Officers should be licensed doctors of medicine or osteopathy.

- A comprehensive, continuing education program that addresses all aspects of MRO function (not just drug abuse recognition) should be developed.

- Professional associations, forensic toxicologists and others should be involved in developing guidelines for continuing education.

- Maintenance of adequate continuing education and training in MRO functions should be required for MROs.

- MROs should be required to develop standard operating procedures that clearly define how all MRO functions are addressed.

- The working group on MRO issues recognized that concerns exist about the time and costs associated with the review of negative test results and that efforts should be made to minimize these factors. Positive results should be released as soon as possible, but ***no consensus*** was reached on the issue of whether MROs must be required to receive and review all ***negative*** drug test results. Until this controversy is resolved, the MROs should continue to receive, review and release positive and negative test results.

- Guidelines should be developed to define confidentiality when any new high technology, electronic transmitting equipment is used in a urine drug testing program.

- While it is recognized that forensic urine drug testing is designed to be part of a drug deterrence program, not a "fitness for duty" program, action should not be taken by an employer or MRO as an employer's agent, on a presumptive-positive (initial screening) only.

- Action should be taken in a drug deterrence program only after a specimen is confirmed positive and verified to be a true positive by the MRO.

- The requirement to report all results as a batch (that is, all samples collected at the same place on the same day reported by the MRO to the employer at the same time) should be discontinued for preemployment and for-cause testing, but remain for random testing.

- All MRO functions and requirements should remain the same as at present if laboratory testing (screening) is performed on-site.

- In unusual circumstances MROs should be able to request, after consultation with the laboratory Director, additional tests on positive specimens that may aid in a complete identification of the drug, metabolite, or of the specimen.

5. PERFORMANCE TESTING

5.1 Specific Issues

- How should Proficiency Test challenge specimens be prepared?

- Open performance testing:

  a. How frequently should open performance testing be conducted?
  b. What are the criteria for acceptable performance?

- Blind performance testing:

  a. How frequently should blind performance testing be conducted?
  b. How should blind PT specimens be prepared and monitored?
  c. How can costs of blind performance testing be controlled?

5.2 Critique

It is generally acknowledged that an external quality control program, or proficiency testing program, is an essential component for the assessment of laboratory competence. Such a program requires the preparation of authentic human urine specimens containing realistic concentrations of the drugs or metabolites to be measured. These specimens should be sent to the laboratory at intervals of sufficient frequency to detect deviations in performance as methods or personnel change or other factors affecting laboratory performance are modified.

An effective PT program contains both open and blind specimen challenges to the laboratory. Open proficiency test specimens are identifiable to the laboratory as PT specimens and contain drugs, metabolites or both in solution. The matrix may be water, "synthetic" urine or water solutions to which certain salts and urinary constituents have been added, or urine itself. Drug-free urine is ideal but difficult and costly to acquire. It has the virtue, however, of simulating a real specimen most closely as to interferences and extraction efficiency, thereby challenging the method used. It is desirable to encourage laboratories to treat open PT challenges ***exactly*** like real specimens. Realistically, in most cases, they are not treated exactly the same since continued certification depends upon obtaining correct results. Generally the results which laboratories report on open PT challenges can be viewed as the best performance of that laboratory.

In order to assess the true proficiency of a laboratory, the PT challenge must be blind to the laboratory. Only then will a PT challenge be received, stored, accessioned, processed and reported as a routine specimen. This is generally recognized but it is a very difficult and costly program to implement. Blind challenges must be human urine rather than "synthetic" or aqueous solutions and must possess no features which allow the analyst to identify them as PT challenges. They must be introduced into the laboratory by clients in a fashion identical to real specimens. The client must then interpret the laboratory performance or transmit the blind PT results to the certifying agency for review and action.

In both open and blind proficiency testing, an effective but realistic number of challenges must be introduced to the laboratory to provide an adequate level of confidence. It is possible to show statistically that an enormous number of blank challenges must be submitted to a laboratory using an assay claimed to have 99.5% accuracy, to establish the probability that a false positive result may be reported. False negative or false positive results are more likely to occur when the concentration of the analyte is targeted near the defined threshold of the assay since a broad standard deviation at these concentrations is less discriminating. The more time and energy laboratories must expend on PT challenges, the more cost is passed through to the client; thus, the number of challenges, together with the concentration of the analyte, are debatable but important considerations in designing a proficiency testing program.

Finally, performance criteria must be developed which are acceptable to the laboratories as well as to the certifying agency. Reporting a PT challenge as positive or negative depends, in part, on the standard deviation of the method used by the laboratory. A maximum acceptable standard deviation for a specific analyte at the threshold of the assay can be used to dictate the limits of analyte concentration ***above*** or ***below*** the threshold acceptable for PT challenges. False positive results are unacceptable because of the implied consequences such a result may have on the tested subject. False negative results are tolerable (up to a limit) but the limit needs to be defined. Establishing the true concentration of the analyte can be done in a variety of ways, such as replicate analyses by selected reference laboratories; using the mean value obtained after all participating laboratories have reported their results. Clients who must submit blind PT challenges may contract with vendors to prepare and monitor the laboratory blind PT results. When this is done, vendors preparing the challenges may be required to establish independent validation of the quality and reliability of prepared PT specimens. On-site testing presents unique problems to the concept of proficiency testing. Open PT challenges can be presented to most on-site, screening-only laboratories. Since quantitation is not done, quantitative accuracy cannot be assessed in this situation. Blind PT challenges will be difficult to

accomplish with most on-site, screening-only laboratories as presently envisioned.

5.3 Consensus Statements

5.3.1 General:

- Proficiency testing is necessary to establish laboratory performance before certification as well as after certification.
- The specific analytes and their concentrations in the specimens must be prepared and monitored by an independent agency and be unknown to the laboratory.
- PT specimens should be processed by the laboratory in the same manner as client specimens.

5.3.2 Specimens:

- Urine used for the preparation of PT specimens should be human, drug-free urine.
- PT specimens should contain verified concentrations of drug, metabolite or both, to enable reliable assessment of PT results.

5.3.3 Open Proficiency Testing:

- For all PT challenges, a false positive result shall be cause for disqualification.
- For all PT challenges, the target concentration for each analyte should be the mean result of the reference laboratories.
- For all PT challenges, laboratories should identify and confirm 90% of total drug challenges, quantitate 80% of total drug challenges within +/- 20% or +/- 2 standard deviations of the target value, whichever is greater, and successfully detect and quantitate 50% of the total drug challenges for any individual drug.

- In the initial PT before certification, a laboratory should analyze 20 PT specimens per cycle for three testing cycles.

- There should be a minimum of 20 challenges [analyte(s)] within a three cycle testing period.

- In the initial PT series before certification, quantitative results may differ by no more than 50% from the target value. If one quantitative result differs by more than this amount, the laboratory should demonstrate that appropriate remedial action was taken and successfully complete an additional PT cycle of 20 specimens.

- After achieving certification, a laboratory should analyze 10 maintenance PT specimens every two months.

- After achieving certification, a laboratory should be permitted one quantitative result that differs by more than 50% from the target value within three consecutive cycles; demonstration that appropriate remedial action was taken, should be required.

5.3.4 Blind Proficiency Testing:

- Blind proficiency testing is the ultimate method for demonstrating the competence of a laboratory since it tests the entire laboratory operation as applied to routine specimens.

- Methods of keeping costs to the client at a minimum while monitoring proficiency effectively should be investigated. A centralized, blind PT program may serve this purpose, but details of such a program would need to be carefully defined.

- The results of blind PT should be sent to the participating laboratory as well as to the certifying agency.

- If the current practice of clients purchasing blind PT specimens from vendors is continued, these specimens should be evaluated by a definitive method (e.g., testing by a minimum of three certified laboratories) before they are sent to client laboratories. The vendor should maintain supporting documentation of stability of the specimens by re-assay throughout the shelf-life of the specimens.

- **Positive blind PT challenges should contain a drug, metabolite, or both at concentrations at least 25% above the threshold for those analytes.**

- **In order to provide a high degree of confidence that performance errors will be detected, the number of blind PT challenges should be adequate. (N.B. Although the Working Group did not suggest a definition of "adequate", floor discussion in a plenary session suggested that blind PT challenges should be 3% of the total submitted specimens by a client, up to a maximum of 100 per month.)**

5.3.5 **On-Site Testing:**

- **Any on-site, screening-only program must participate in open and blind proficiency testing programs.**

6. LABORATORY INSPECTIONS

6.1 Specific Issues

- What is the most appropriate number of inspections, number of inspectors for each inspection team, and estimated cost of inspections?
- How can laboratory inspections be conducted fairly and uniformly?
- Can turnaround time between completion of an inspection and informing the laboratory of certification or non-certification be improved?
- Should there be an exit interview with the laboratory director by the inspection team and what limitations, if any, should be placed on topics for discussion?
- Are there alternatives to inspections to ensure that laboratories meet criteria and standards set by the certification program?
- What should be the residency requirements for the scientific director of the laboratory?
- Is a baccalaureate degree in medical technology appropriate for a certifying scientist?

6.2 Critique

Laboratory inspections appear to be unavoidable as part of the laboratory certification process. Some aspects of laboratory operations such as size, workload, staffing and types of equipment, can be described relatively easily in written form. Other important features such as security, accessioning techniques, chain-of-custody and many others are less easily described but must be visualized in order to determine if they meet pre-set standards.

Since laboratories vary widely as to size, workload and staffing needs, the number of inspectors and the time allotted for an inspection may also vary. Some urine drug testing laboratories occupy multi-story buildings, operate more than one shift each day and process thousands of specimens each week. Inspection of such an operation is more demanding than that of a three room laboratory, managing a workload of hundreds of specimens with a relatively small staff. The differences between these

examples are obvious, yet both laboratories must meet the same standards. Since standards required for certification are the same but the manner by which laboratories meet these standards may vary, it is important that different inspectors carry out all inspections uniformly. How can this be achieved? Some have suggested that laboratory directors serve as inspectors of other laboratories; however, some laboratories object to being inspected by a competitor. Another plan is to select qualified individuals and train them to a set of uniform criteria designed to identify flaws and allow judgements as to how standards should be met. Such trained inspectors, in turn, may be lost to the pool of inspectors since they become leading candidates for commercial laboratory director positions. Obviously, inspectors must be experienced, qualified scientists; however, such individuals are accustomed to thinking independently and may judge laboratory performances according to their own, unique standards.

The number and quality of inspectors and the time spent conducting an inspection contribute to the cost of a certification program. Should the inspectors be paid for the time they spend conducting this service? Should inspectors be selected from a geographical location near to the laboratory? How frequently must a certified laboratory be re-inspected? The cost of the program is ultimately passed through to clients but high costs impact most unfavorably on small laboratories.

The size or complexity of a laboratory operation may also contribute to strikingly different approaches to meeting certification standards. Personnel qualifications may vary in individuals conducting tasks of equal responsibility. Should educational training carry more weight than forensic experience or technical skill at the bench? Are automated, computer-controlled operations equal to manual manipulations? If urine drug testing is only a small part of a laboratory operation, must the scientific director be present at all times? These are but a small sample of the differences in laboratory operations which inspectors must assess in judging laboratory acceptability.

Once the inspection is complete, other factors become evident and require debate. Should the inspectors share their findings with the laboratory director before they leave? Do the inspectors make pass or fail decisions or should this be left to a higher level of review? Perhaps a deficiency is so minor it can be corrected easily. An exit interview might also lead to rapid correction of a misinterpreted observation by an inspector. Is the basic purpose of the inspection regulatory in nature or to improve laboratory operation? Is it both? Laboratories need to rectify deficiencies rapidly to remain competitive. Can the process of filing an inspector's report, reviewing the report and arriving at a decision and notification of the laboratory be shortened?

Finally, are there alternatives to the inspection process for evaluating laboratory credibility? Certification standards are set as a public service

to identify a technical operation as meeting certain minimum standards to enable individuals not trained in technical matters to make intelligent choices for laboratory services.

The costs and imperfections of the inspection process must be balanced against the benefits of rectifying errors and improving substandard operations which, unless corrected, blunt the deterrent effect of urine drug testing.

6.3 Consensus Statements

6.3.1 Eligibility Requirements:

- To be eligible for inspection, a laboratory should:

  a. Satisfactorily complete 3 performance testing surveys (See: Performance Testing).
  b. Have a scientific director with the following educational and (or) experience qualifications:
     1. Certified in toxicology by ABFT, ABCC-T or by other, comparable certifying agencies, OR possess a doctorate degree and two years experience in the toxicological analysis of biological material, OR possess a master of science or baccalaureate degree and six years experience in the toxicological analysis of biological material, two or more years of which were as a supervisor with responsibility for interpretation of results.
     2. Knowledgeable in forensic matters and experienced in:
        - judicial or administrative proceedings in drug or medical issues, OR
        - author of research publications or presentations at scientific meetings on drugs of abuse.
     3. Capable of reviewing, validating and certifying test data.
     4. All of the above requirements should be documented and available for review.

6.3.2 Frequency of Inspections:

- An initial inspection should occur before certification.

- Beginning from the time of certification, inspections should occur at six, twelve, eighteen and twenty-four months; following these two years, inspections should occur annually.

- More frequent inspections of particular laboratories may be required if the certifying agency deems it necessary.

6.3.3 Inspectors:

- A minimum of three inspectors should participate in the initial inspection, before certification of the laboratory.
- A minimum of two inspectors should participate in routine, maintenance inspections after certification of a laboratory.
- The designated team leader of the inspection team should have qualifications equivalent to a laboratory scientific director.
- If inspectors are carefully selected and trained to meet the same standards, there should be no difference in the objectivity and ability of paid or volunteer inspectors. Training programs however should stress the critical need for inspection criteria to be applied uniformly.

6.3.4 Exit Interview:

- An exit summation conference between the inspection team and the person responsible for the toxicology laboratory operations should present the detected deficiencies and any other identified problems.
- The laboratory should have the opportunity to clarify misunderstandings at the summation conference.

6.3.5 Laboratory Facilities:

- The laboratory should be secure at all times.
- The test of security should require evidence that urine specimens, aliquots and records are maintained in an environment that assures reasonable freedom from tampering, alterations and substitution. Any breach of the security system should be readily detectable.
- Available laboratory space should not compromise the quality of work, quality control activities or the health and safety of the employees.

6.3.6 Data Review:

- During an inspection, the inspectors should review data supporting positive and negative reports from urine drug testing.

- Supportive analytical data from the prior 60 days should be readily available for inspectors to review in the laboratory.

6.3.7 Reporting Negative Results:

- The individual who reports validated negative results of initial (screening) tests, may be appointed by the Responsible Person.

- The individual who validates the initial (screening) test results should have the following training and experience:

  a. The minimum of a baccalaureate degree in the chemical or biological sciences or medical technology or equivalent.
  b. Training, experience and thorough understanding of the theory and practice of the initial (screening) procedures used, including:
     - quality control practices and procedures
     - the review, interpretation and reporting of negative initial (screening) test results
     - maintenance of chain-of-custody, and
     - proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

6.3.8 Reporting Positive Results:

- The individual who validates the confirmatory test results should have the following training and experience:

  a. The minimum of a baccalaureate degree in the chemical or biological sciences or medical technology or equivalent.
  b. Training, experience and thorough understanding of the theory and practice of the confirmatory procedures used, as well as the initial (screening) procedures used including:

- quality control practices and procedures
- the review, interpretation and reporting of confirmation test results
- maintenance of chain-of-custody, and
- proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

6.3.9 Cost:

- The cost of laboratory inspections should be reduced to a reasonable level. (N.B. The Working Group does not recommend an estimated cost amount, but expresses the opinion that present costs are too high.)

- Inspection costs should reflect the shortened time and fewer inspectors necessary for small laboratories.

6.3.10 Uniform Certification Standards:

- Laboratories seeking certification should be subjected to the same standards even though they may be monitored by different certification agencies.

- The Department of Health and Human Services should have an oversight function to monitor the certification agencies.

- Certificates should be issued by the Secretary of Health and Human Services.

- The Secretary of Health and Human Services should rapidly establish methods to grant equivalency to acceptable accrediting agencies.

6.3.11 On-Site Testing (Screening Only) Laboratories:

- On-site laboratories should meet the basic forensic standards for specimen collection, chain-of-custody documentation, and security.

- On-site laboratories should be subject to inspection.

- **Validation of test results and reporting should be done by an individual meeting the criteria of a laboratory supervisor.**

- **All presumptive positive specimens should be submitted to a certified laboratory for confirmation, while maintaining documented chain-of-custody.**

- **On-site laboratories should participate in open and blind performance testing surveys.**

7. MONITORING LABORATORY PERFORMANCE

7.1 Specific Issues

- Are there alternate methods for monitoring laboratory performance?
- How does open performance testing monitor laboratory performance?
- How do laboratory inspections relate to monitoring laboratory performance?
- How does blind performance testing monitor laboratory performance?
- What support systems are important?
- What sanctions should be imposed against laboratories not in compliance?
- What is the balance between loss of certification and remedial action?
- How can on-site (screening only) testing facilities be monitored?

7.2 Critique

Traditionally, laboratory performance has been monitored by the triad of open proficiency testing, inspection and blind proficiency testing. Other, practical procedures for accomplishing this task have been elusive but innovative methods may be feasible.

Performance testing and laboratory inspections have been dealt with individually elsewhere in this report. [2] The judicious use of these tools may be the best procedure for monitoring total laboratory performance. Open proficiency testing can focus on optimal analytical accuracy, particularly quantitative, confirmation procedures. Inspection provides a means of confirming that laboratories are using all aspects of good laboratory practices effectively and appropriately. For example, the best analytical technique is useless if applied to the wrong specimen; or, the legal defense of a test result by testimony of personnel with limited

[2] See Chapters 5 and 6.

knowledge and experience may negate a positive result. How large numbers of specimens are managed and confirmation of personnel qualifications are two example items best verified by personal observation. Blind proficiency testing can ensure that a laboratory handles routine specimens in a credible manner.

If, indeed, these are the only effective means by which laboratory performance can be monitored, perhaps they can be utilized more effectively and economically. The high cost of laboratory certification is a frequent criticism. The slowness of the process is annoying to aggressive laboratories eager to gain access to markets restricted to certified laboratories. The reluctance of regulatory programs to assist laboratories in rapidly indentifying deficiencies and improving their performance, frustrates some laboratory directors with limited experience in forensic affairs. After almost two years of experience in applying inspections and open and blind PT programs to laboratory certification decisions, it may be possible to look at the process with a view to fine-tuning, eliminating redundancy and gaining the maximum return from each aspect of laboratory performance monitoring.

The problem of remedial action against a laboratory which no longer meets minimum standards is most difficult. Should there be degrees of penalties, depending upon the seriousness of the infraction? Are technical errors more serious than clerical ones, even though either may be responsible for ascribing drug use to the wrong individual? What type of error should mandate decertification of a laboratory? Should a grievance procedure be established to permit laboratories to defend themselves against alleged improper accusations? What happens to the specimens being sent to the suspect laboratory during the grievance process? What about the positive results reported by the suspect laboratory before the infraction was discovered? These, and other problems, must be anticipated in any certification program. If laboratories which no longer meet minimum certification standards continue to operate, the credibility of the program is seriously damaged. In addition, the public must be made aware of laboratories which may not be able to consistently meet minimum standards for urine drug testing.

Finally, the difficult problem of monitoring on-site (screening only) laboratory performance must be addressed. The rare, but important situations which require rapid decisions relating to drug use by workers in responsible, safety-related positions, frequently cannot wait for the necessary delay required by confirmation testing. Since the test itself may be conducted at a portable laboratory, in the field or at the job site, monitoring such a laboratory is a unique challenge. The effectiveness of this type of urine drug testing must be maintained without unduly restricting the rights of the worker.

7.3 Consensus Statements

The Working Group identified its task as defining a process which monitors laboratory performance after the laboratory is certified but does not deal with laboratory performance before certification.

7.3.1 Organization of the Program:

- **After certification, a single agency should monitor the performance of all laboratories certified for urine drug testing.**
- **Criteria for performance should include open PT, blind PT and inspections.**
- **The monitoring agency should be supported by an advisory group, representing all appropriate involved professions meeting frequently at regular scheduled intervals to provide policy advice and problem review.**

7.3.2 Open Performance Testing: (See: Performance Testing Section)

- **Specimens should be processed as closely as possible to the laboratory's standard operating procedure for client specimens, with only minor accommodations such as chain-of-custody forms, reporting forms, container labels, made as necessary.**
- **Frequency of testing should be quarterly.**
- **Results should be completed and delivered to the monitoring agency no later than the 10th day following receipt of the open PT specimen in the laboratory.**
- **The monitoring agency should return a report which summarizes the laboratory's performance as compared to the group mean result, within 30 calendar days following receipt of the result.**

7.3.3 Laboratory Inspections: (See: Laboratory Inspection Section)

- **Inspections should be performed every six months for the first two years after initial certification, and annually thereafter.**

- There should be rapid and detailed feedback to laboratories of their performance.

- The inspection team should be permitted to provide feedback of information to the laboratory's responsible person while the inspectors are on site, in accordance with established policies of the monitoring agency.

- Major changes in the laboratory operation, such as change in the physical plant or location, change in the responsible person, change in ownership or name of the laboratory or other, substantive changes, should be reported to the monitoring agency within five working days of the change.

7.3.4 Blind Performance Testing: (See: Performance Testing Section)

- Develop a uniform set of specifications for blind PT specimens.

- Target values of blind PT specimens should be validated and monitored throughout the shelf-life of the specimen batch.

- Develop a mechanism to submit blind PT specimens and to receive and evaluate reports of blind PT results.

- Develop a mechanism to return blind PT performance results to the laboratory.

- Introduce blind PT specimens proportionally over time to include a minimum of 3% of the number of client specimens.

7.3.5 Communication:

- A variety of communication systems, such as a newsletter, electronic bulletin boards, regularly scheduled meetings of representatives of certified laboratories and the monitoring agency, should be explored and developed in order to share information such as statistical trends and evaluation of PT results, as well as notice of timely and contemporary issues of importance in urine drug testing.

7.3.6 Response to Failure of Certified Laboratories:

- Detection of an apparent false positive test result is of such importance that immediate action should be initiated to investigate the cause.

- Investigation should be completed by the laboratory within seven calendar days of receipt of notice.

- Failure to resolve the cause of a false positive result to the satisfaction of the monitoring agency should result in placing the laboratory on probation; failure to satisfy the conditions of probation may result in suspension or revocation of certification.

- Failure or inability of a laboratory to adequately identify and quantitate analytes (i.e., analytical errors) may result in probation, suspension or revocation of certification. Analytical errors include false negatives, failure to identify and confirm 90% of total drug challenges, failure to quantitate at least 80% of total drug challenges at the greater of +/- 20% or +/- 2 standard deviations of the *participant* group mean, or inability to successfully detect and quantitate 50% of the total drug challenges for any individual drug. (Failure to quantitate within 50% of the calculated ***reference*** group mean is not an analytical error for this purpose.)

- Failure of a laboratory to pass an inspection may result in probation, suspension or revocation of certification.

- Failure of a laboratory to notify the monitoring agency of substantive changes in the laboratory operation may result in probation, suspension or revocation of certification.

- During probation, a laboratory remains certified while the monitoring agency reviews data and develops a corrective action plan and timetable; failure to satisfy the conditions of probation results in suspension.

- During suspension of certification, a laboratory may test PT specimens, but may not process or test any client specimens, such specimens on hand may be forwarded to another certified laboratory for analysis.

- When a certified laboratory is suspended, the laboratory should immediately notify all clients of the suspension; failure to notify clients should result in revocation of certification.

- If a laboratory suffers revocation of certification, the entire initial certification process should be completed before further testing can be initiated.

- The monitoring agency should publish an updated list of certified laboratories on a monthly basis.

7.3.7 **Screen Only Initial Testing Facilities:**

The Working Group assumed that various elements of the regulatory system for these facilities and their work activities will be developed by other groups and in other forums. They, therefore, limited their consideration to monitoring drug screening only. They emphasize that these facilities should only be allowed where safety issues demand the most rapid turnaround time, justifying the risks to the client inherent in unconfirmed test results and the considerable difficulties in achieving accurate testing that such facilities create.

- Performance monitoring criteria should include performance testing, facility inspections and split sample re-analysis at a certified laboratory.

- The analytes to be tested include those drugs and metabolites authorized through the HHS program.

- The facility should be inspected and certified initially, then re-inspected annually.

- The collected urine specimen should be split into two equal portions, with appropriate chain-of-custody and sealed containers.

- The facility may choose one of the two following procedures after proper collection of the split specimen:

a. Complete re-analysis of all samples.
   1. The facility should analyze one of the two concurrently collected specimens. The facility should submit the other specimen to a certified laboratory for analysis, including screening and confirmation.
   2. Reports of both test results should be forwarded to the agency designated to monitor facility performance for review and appropriate action.

b. Partial re-analysis of samples.
   1. The facility should analyze one of the two concurrently collected specimens. For all specimens which screen positive, and 20% of those which screen negative, the facility should send the other specimen to a certified laboratory for analysis, including screening and confirmation.
   2. Performance testing specimens should be analyzed with each batch. PT specimens should comprise a minimum of 10% of the number of specimens per batch (or at least 1). PT specimens should challenge all drugs tested.

3. Specifications for performance testing specimens should be comparable to those utilized by certified laboratories.
4. Reports of performance test specimens from the facility, as well as the certified laboratory, will be forwarded to the agency which monitors facility performance, for review and appropriate action.

- The monitoring agency should develop appropriate sanctions for inadequate performance.

APPENDIX A

GLOSSARY OF TERMS

ABCC-T - The American Board for Clinical Chemistry in Toxicology. A group of competent clinical chemists which establishes qualifications for clinical chemists who conduct toxicological tests. Clinical chemists who meet these qualifications and pass a written examination earn the privilege of identifying themselves as Diplomates of the Board.

ABFT - The American Board of Forensic Toxicology. A group of competent forensic toxicologists which establishes qualifications for certification in this field. Forensic toxicologists meeting these qualifications who pass a written examination, earn the privilege of identifying themselves as diplomats and using the acronym DABFT as a means of identifying achievement of this status.

Aberrant Results - Analytical results which deviate from a normal or usual trend. These are not necessarily false results but may indicate a quantity of drug much greater or less than that reported by other laboratories.

Accessioning - A process by which a laboratory receives, identifies, and properly removes a portion of a specimen for testing while maintaining the true identity of the specimen.

Accrediting Agencies - Organizations, either public or private, professional societies or government agencies, which establish standards for certain operations, select applicants who wish to become accredited and examine them by a variety of methods to determine whether the minimum standards are met or exceeded. Accrediting agencies may also revoke accreditation if minimum standards are not maintained.

Accuracy - The closeness with which results agree with a known true value of the quantity being measured.

Agency - An organization, or administrative office, which is empowered to act for another, usually with specific functions.

Aliquot - A portion of a specimen or sample used for testing.

Amphetamines - A term generally used to include amphetamine and methamphetamine. Other phenethylamines, not all of which are abused, may cross-react with some antibodies used in immunoassay test kits and may be included in this group.

d-Amphetamine - Amphetamine is a specific phenethylamine of known structure which exists in two isomeric forms. The **d**, or **dextro** form (rotates polarized light to the right), is a potent central nervous system stimulant and is subject to abuse.

l-Amphetamine - The **l, or levo**, isomer of amphetamine (rotates polarized light to the left), is not a potent central nervous system stimulant and is not subject to abuse.

Analyte - The chemical component being measured in an analysis.

Assay - The measurement of the quantity of a chemical component.

Barbiturates - A class of drugs used in medicine as hypnotic agents to promote sleep or sedation. Some are also useful in the control of epilepsy. All are central nervous system depressants and are subject to abuse. Depending upon their potency they are classified as Schedule II or Schedule III drugs.

Batch Reporting - Urine specimens for drug testing are frequently sent to the laboratory in groups or "batches." Test results are generally reported on all specimens in a batch simultaneously, rather than reporting the negatives first then, after a delay while they are confirmed, reporting the positive results. Batch reporting improves confidentiality by helping to avoid identifying those individuals whose test must be confirmed.

Batch Requirement - See BATCH REPORTING.

Benzodiazepines - A class of drugs used in medicine as minor tranquilizers which are frequently prescribed to treat anxiety. They are central nervous system depressants and are subject to abuse.

Benzoylecgonine - A metabolite of cocaine which is readily excreted in the urine where its detection implies cocaine use.

Blind Performance Testing - See PERFORMANCE TESTING. When conducted in a blind fashion, the laboratory, and particularly, the analyst, is not aware that the specimen being tested has been submitted specifically to monitor laboratory performance.

Blind Proficiency Testing - See BLIND PERFORMANCE TESTING.

Blind QC - Control material which is introduced into a batch of specimens in such a manner that the analyst is unaware that it is not a real specimen. This is done by the laboratory director or by the quality control supervisor in order to make sure that the control material is not given special treatment.

Cannabinoids - The psychoactive substances found in the common hemp plant, or **Cannabis sativa**. Most of the psychological effects are produced by delta-9-tetrahydrocannabinol. In urine drug testing, the prior use of cannabinoids is established by the detection of metabolites of cannabinoids. These are generally inactive but are present in greater quantities. The most abundant metabolite is ll-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid, sometimes referred to as 9-carboxy-THC, toward which most immunoassays and confirmation procedures are directed.

Certified Copy - A copy of a document (NOT the original), such as a laboratory report or chain of custody form, which is attested as being a true copy by a responsible official.

Certified Laboratory - A laboratory which has met certain minimum performance standards set by an accrediting agency, and has received a certificate to verify this fact.

Certified Reference Material - A material or substance or drug, one or more of whose property values are certified by a valid procedure, or accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body.

Certifying Official - The individual who reviews all test results, quality control results and other appropriate data relating to testing a specific specimen and, if acceptable, certifies in writing that the test result is correct.

Chain-of-Custody - Procedures to account for the integrity of each urine specimen, or aliquot thereof, by tracking its handling and storage from point of specimen collection to the final disposition of the specimen. Documentation of this process must include the date and purpose each time a specimen or aliquot is handled or transferred and identification of each individual in the chain of custody.

Challenge - A urine specimen submitted to a laboratory as part of a Performance Testing program.

Chromatography - Any of a variety of techniques used to separate mixtures of drugs and their metabolites and other chemicals into individual components based on differences in their relative affinities for two different media: a mobile phase and a stationary phase. In **gas chromatography**, the mobile phase is an inert gas such as nitrogen or helium and the stationary phase is a high-boiling liquid bound to fine particles packed in a glass column, or bound to the inner surface of a glass capillary column.

Cocaine - An alkaloid, methylbenzoylecgonine, obtained from the leaves of the coca tree (**Erythroxylon sp.**). It is a central nervous system stimulant that produces euphoric excitement; abuse and dependence constitute a major drug problem. It is used as the hydrochloride salt as well as the free base.

Coefficient of Variation - The relative standard deviation or the standard deviation expressed as a percentage of the mean. The coefficient of variation (cv) is commonly used as a measure of precision for laboratory procedures.

Collection Site - A place designated where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Confirmation - The process of using a second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy.

Creatinine - A substance formed by the spontaneous breakdown, in the body, of phosphocreatine and is excreted in the urine. The rate of creatinine excretion is a function of body muscle mass and is relatively constant but dependent on the health, sex and age of the individual.

Cross Reactivity - The degree to which an antibody interacts with antigens other than the one used to produce the antibody. This is a property of nearly all naturally derived antibodies.

Cut Off - The defined concentration of analyte in a specimen at or above which the test is called positive and below which it is called negative. (See THRESHOLD) This concentration is usually significantly greater than the sensitivity of the assay (See SENSITIVITY and LIMIT OF DETECTION).

DABFT - SEE ABFT.

Delta-9-THC Acid - See CANNABINOIDS.

l-Desoxyephedrine - The **levo** isomer of desoxyephedrine which is another name for methamphetamine. The l isomer is used as a nasal decongestant in inhalers available for purchase without a prescription. It has little, if any, abuse potential but may give a positive test result with some immunoassay antibodies. Special procedures must be used during confirmation by GC/MS in order to avoid confusion with **d**-desoxyephedrine or methamphetamine.

Deterrent Program - A program, such as a urine drug testing program, which has as its goal to deter individuals from the abuse of drugs.

Documentation - A printed or written record retained as support or proof of claims made in reporting test results or in the laboratory certification process.

Drug Challenge - See CHALLENGE.

Drug Metabolite - A modified form, or degradation product of a drug produced by a metabolic process.

EAP - See EMPLOYEE ASSISTANCE PROGRAM.

Electronic Bulletin Board - A networking system which enables computer operators to rapidly communicate by means of personal computers with other operators having access to the same "bulletin board." Access generally requires the use of a password but may not be sufficiently secure to ensure confidentiality.

Employee Assistance Program - A program designed to assist employees with drug abuse, or other problems by means of counseling, treatment or referral to more specific centers.

Ethyl Alcohol - Ethanol, or C_2H_5OH, the member of the alcohol series of chemicals which is used in alcoholic beverages. It is less toxic than other members of this series, but it is a central nervous system depressant and has a high abuse potential.

False Negative - A test result which states that no drug is present when, in fact, a tested drug or metabolite is present in an amount greater than the threshold or cut-off amount.

False Positive - A test result which states that a drug or metabolite is present when, in fact, the drug or metabolite is not present or is in an amount less than the threshold or cut-off value.

FDA Accepted Screening Assay - Test kits designed to be used on body fluids for diagnostic purposes must be approved by the FDA for commercial distribution and used according to the manufacturer's instructions.

For-Cause Testing - Urine drug testing of an employee or subject who shows behavioral changes or other evidence of probable drug use.

Forensic - Suitable for a court of law or public debate or argument.

Fortified Samples - Urine or other specimens to which drugs or metabolites have been added in addition to what may already be present.

GC-MS - An abbreviation for the instrumental technique which couples the powerful separation potential of gas chromatography with the specific characterization ability of mass spectroscopy.

Guidelines - Standards by which a policy or course of action is determined. In urine drug testing, this term generally refers to the Mandatory Guidelines for Federal Workplace Drug Testing Programs as published in the Federal Register, volume 53, Number 69, pp 11970-11989, April 11, 1988.

Immunoassay - The measurement of an antigen-antibody interaction utilizing such procedures as immunofluorescence, radioimmunoassay, enzyme immunoassay or other nonradioisotopic techniques. In drug testing, the antigen is a drug or metabolite and its corresponding labeled analog; the antibody is a protein grown in an animal and directed towards a specific drug, metabolite or group of similar compounds.

Initial Testing Procedures - The initial test, or screening test, is used to identify those specimens which are negative for the presence of drugs or their metabolites. These specimens need no further examination and need not undergo a more cosily confirmation test.

d-, l-Isomer Issue - Many drugs exist in more than one isomeric form. Optical isomers are identical except that their functional groups are oriented in space differently. They are frequently described as mirror images of each other and rotate polarized light in opposite directions (See AMPHETAMINE). Generally only one isomer is active and exhibits a potential for abuse. Since most immunoassays fail to discriminate between these isomers, the confirmation test must do so which may require a procedure other than GC-MS.

Limit of Detection - The minimum amount of an analyte which can be detected with confidence by a testing procedure.

Limit of Quantification - The minimum amount of an analyte which can be quantified by a testing procedure, while conforming to the required coefficient of variation of the procedure.

Linearity - A straight-line relationship between analyte concentrations and the instrument response, in which a change in concentration causes a proportional change in the response.

Mass Spectrometry - Analysis using an analytical instrument that provides accurate information about the molecular mass and structure of complex molecules. This technique can identify and quantify extremely small amounts of drugs or metabolites by their mass-fragment spectrum.

Mean Result - If replicate analyses are conducted on a specimen, the sum of all of the quantitative results divided by the number of replicate analyses gives the mean result.

Medical Review Officer - A licensed physician responsible for receiving laboratory results generated by a drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Methadone - A synthetic opiate with action similar to that of morphine and heroin except that withdrawal is more prolonged and less severe. It is used in methadone maintenance programs as a substitute for heroin in the treatment of addicts.

d-Methamphetamine - The optical isomer of methamphetamine (desoxyephedrine) which rotates polarized light to the right (**dextro**) and is the active isomer. It is a central nervous system stimulant and has a strong potential for abuse. Recently it appears to be gaining popularity for illicit use in the form of "ice."

Methaqualone - A hypnotic drug unrelated to the barbiturates but used as a sedative and sleeping aid. Formerly it was a widely abused drug but seems to be less popular in recent years. It is also known by its trade name Quaalude.

Minimum Performance Criteria - Although the HHS Guidelines and standards set by other certifying agencies are criticized, at times, for their detail and rigor, laboratories which achieve certification are identified as having met the minimum performance criteria of the certifying agency and may, in fact, meet self-imposed criteria of a higher standard.

Monitoring - To check constantly on the accuracy and general performance of a laboratory, instrument or analyst.

NIDA - The National Institute on Drug Abuse.

NIST - The National Institute of Standards and Technology (formerly the National Bureau of Standards).

Non-Contact Positive - When a medical review officer receives a positive test result, extensive efforts are made to contact the employee before reporting the result. If it is not possible to contact the employee, the result will be reported to the employer as a "non-contact positive" result.

On-Site Screening - In those situations in which it is desirable to learn urine drug test results quickly, the preliminary immunoassay screening test may be conducted at the worksite.

Open Performance Testing - Performance testing which is done with the knowledge of the analyst (see PERFORMANCE TESTING).

Open Proficiency Testing - See OPEN PERFORMANCE TESTING.

Open QC Program - A quality control program designed by the quality control supervisor or responsible person which is known to the analysts and technologists and is implemented to detect the random and systematic errors which may occur throughout the drug testing process.

Opiate - A term used to designate drugs derived from opium such as morphine and codeine, together with the semisynthetic congeners such as heroin. Immunoassay kits for opiates are generally directed to detect morphine but crossreact with other opiates as well.

Osteopathy - A branch of medicine that utilizes a system of therapy based on accepted medical practices and emphasizes the importance of normal body mechanisms and manipulations to detect and treat disease.

Oversight Inspection Team - A group of experienced individuals who monitor the performance of on-site screening laboratories.

Passive Inhalation - The innocent exposure of non-smoking subjects to side-stream smoke from active smokers, thereby raising the possibility that a non-user of marijuana may test positive for metabolites of delta-9-tetrahydrocannabinol.

Peer Review Committee - A committee made up of individuals with similar training and experience to that of a Responsible Person, to review the performance of the Responsible Person or the laboratory under the direction of a Responsible Person.

Performance Testing - A program designed to monitor the analytical accuracy and precision of a drug testing laboratory. This is done by periodically submitting challenges of human urine fortified with drugs or metabolites of drugs to the laboratories being monitored. Test results must conform to predetermined limits of accuracy and precision when compared to the test results of reference laboratories or to the mean result of all participating laboratories.

pH - The negative logarithm of the hydrogen ion activity in solution. This is a measure of acidity of a specimen. The lower the number, the more acidic is the specimen. The pH of random urine may range between 4.5 and 8 pH units.

Phencyclidine - One of the most dangerous of the hallucinogenic, illicit drugs, most often referred to as PCP. Psychotic reactions such as extreme anxiety or panic and hypertensive crisis and seizures are common; many fatalities have occurred through its abuse.

Precision - A measurement of the agreement between repeated measurements. The standard deviation, variance or coefficient of variation may be used as a measure of precision.

Pre-Employment Testing - The widespread practice of conducting urine drug testing on applicants for jobs in order to minimize the likelihood of employing a drug abuser.

Presumptive Positive - A positive screening or immunoassay test is presumptive and then should be confirmed by a different, more specific test.

Primary Standard - A reference material or, better, a certified reference material upon which a test procedure is based.

Probation - The time during which a certified laboratory is given an opportunity for informal review of procedures suspected of being in violation of certification criteria which could lead to suspension or revocation of the laboratory's certification.

PT Program - See PERFORMANCE TESTING.

Qualitative Analysis - Relating to a test or measurement that determines the presence or absence of specific drugs or metabolites in the specimen.

Quality Assurance - A program by which good technical procedures are provided to ensure good quality laboratory services. These procedures include pre-analytical conditions and variables, analytical variables and control of the analytical quality by statistical methods.

Quality Control - A system instituted to maintain the output of a technical operation at a level that has been established as acceptable. It involves the setting of quality standards, continual appraisal of conformance to these standards, and, in the absence of conformance, taking corrective action to establish or maintain the predetermined levels of performance. Both intra- and interlaboratory quality control (QC) are utilized.

Quantitative Analysis - The accurate determination of the quantity of drug or metabolite present in a specimen.

Racemic - A mixture of two, mirror image, optical isomers of a drug or metabolite resulting in optical inactivity of the mixture.

Random Testing - Unannounced, random selection of candidates to be tested.

Real Samples - Urine specimens collected from real subjects for testing purposes in contrast to open or blind PT specimens, control specimens, calibrators, etc.

Reanalysis - A specimen which is taken from storage for a repeat analysis by request of the medical review officer or because of a legal challenge.

Reference Group - A group of laboratories testing the same PT specimens in order to establish the mean concentration of analyte.

Remedial Action - a) Action taken by a laboratory to correct a deficiency observed during an inspection. b) Action taken by an analyst to correct an assay procedure when a control specimen is found to be out of control.

Responsible Person - A responsible person is an individual with defined qualifications who assumes professional, organizational, educational and administrative responsibility for the laboratory's urine drug testing facility.

Revocation of Certification - A certified laboratory may have its certification revoked if such a step is necessary to ensure full reliability and accuracy of drug tests and the accurate reporting of drug tests. The factors to consider prior to revocation are variable as are the period and terms of the revocation.

Safety Sensitive Positions - Occupational positions which are deemed acutely sensitive to safety considerations such as airline pilots, nuclear reactor operators, train crews, etc.

Schedule II Drugs - Refers to drugs in Schedule II of the Controlled Substance Act which have a high potential for abuse with severe liability to cause psychic or physical dependence, but have some approved medical use.

Scientific Director - The person responsible for the technical operation of the laboratory. This individual must be knowledgeable in QC procedures and appropriate remedial action, analytical procedures and all aspects of the testing process.

Screening - See INITIAL TESTING PROCEDURES.

Security - The process by which specimens are protected from tampering, contamination and mix-up while maintaining confidentiality of the test results. The process should be organized in such a way that unauthorized persons do not have access to specimens and any breach of security is immediately recognizable.

Sensitivity - The smallest concentration of a drug or metabolite which can be reliably detected by a particular assay method (See LIMIT OF DETECTION).

Specific Gravity - The ratio of the density of urine to the density of water at a specified temperature. The specific gravity of random urine specimens ranges between 1.002 and 1.030 at body temperature, depending on fluid intake.

Specificity - The ability of a particular test to identify a drug or metabolite without interference or cross reactions.

Specimen - The entire quantity of material (e.g., urine, blood) collected for analysis.

Split Specimen - The practice of dividing a urine specimen into two portions, one of which may be submitted for analysis and the other preserved by freezing for the confirmation analysis or reanalysis.

Substance Abuse Assessment - A medical and psychological review and examination of a subject to determine the extent, if any, of chemical dependency (See EAP).

Survey - A cycle of PT challenges.

Suspension of Certification - If revocation of a laboratory's certification is contemplated and immediate action is deemed necessary, suspending the laboratory's certification may be instituted until certification is reinstituted or revoked.

Target Value - The amount of analyte weighed into a specimen during the preparation of a PT specimen which results in an intended concentration. The concentration is confirmed by analysis in a reference laboratory. (See VERIFIED DRUG CONCENTRATION.)

Team Leader - The designated leader of a team of laboratory inspectors.

Testing Cycle - The time during which a group of PT challenges are submitted and processed by a laboratory.

Testing Protocol - The standard operating procedure (SOP) by which a laboratory conducts a specific drug analysis.

THC - Delta-9-tetrahydrocannabinol, the most active cannabinoid (See CANNABINOIDS).

Threshold - See CUT-OFF.

Turnaround Time - The amount of time between receiving a specimen and reporting the test result.

Validation - The process by which an analytical technique is proven as to its accuracy, precision, sensitivity, linearity and selectivity.

Verified Drug Concentration - The confirmation that a target value has been achieved in preparing PT specimens, calibrators or blind controls. This is generally done by careful analyses by reference laboratories.

Volatile Solvents - Low boiling liquids which evaporate rapidly. The fumes from these solvents may be inhaled deliberately by individuals who have developed a dependency to these chemical substances.

APPENDIX B

Analytical Methods Working Group

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Part IV

Department of Health and Human Services

Alcohol, Drug Abuse, and Mental Health Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS

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Authority: E.O. 12564 and sec. 503 of Pub. L. 100-71.

Subpart A—General

1.1 Applicability.

(a) These mandatory guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101 (3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2)); [illegible]

(3) And any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(b) Any agency or component of an agency with a drug testing program in existence as of September 15, 1986, and the Departments of Transportation and Energy shall take such action as may be necessary to ensure that the agency is brought into compliance with these Guidelines no later than 90 days after they take effect, except that any judicial challenge that affects these Guidelines shall not affect drug testing programs subject to this paragraph.

(c) Except as provided in 2.6, Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(d) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(e) These Guidelines do not apply to drug testing conducted under legal authority other than E.O. 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

(f) Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

1.2 Definitions.

For purposes of these Guidelines the following definitions are adopted:

Aliquot A portion of a specimen used for testing.

Chain of Custody Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved agency chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt of the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody.

Collection Site A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection Site Person A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function.

Confirmatory Test A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability.

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and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Initial Test (also known as Screening Test) An immunossay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Permanent Record Book A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

Reason to Believe Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of E.O. 12564.

Secretary The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

1.3 Future Revisions.

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the Federal Register.

Subpart B—Scientific and Technical Requirements

2.1 The Drugs.

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA) but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

(1) Federal agency applicant and random drug testing programs shall at a minimum test for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs are also authorized to test for opiates, amphetamines, and phencyclidine; and

(3) When conducting reasonable suspicion, accident, or unsafe practice testing, a Federal agency may test for any drug listed in Schedule I or II of the CSA.

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12564, Pub. L. 100-71, and these Guidelines shall be used only to test for those drugs included in agency drug free workplace plans and may not be used to conduct any other analysis or test unless otherwise authorized by law.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

2.2 Specimen Collection Procedures.

(a) Designation of Collection Site. Each agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) Security. Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(c) Chain of Custody. Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) Access to Authorized Personnel Only. No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) Privacy. Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided.

(f) Integrity and Identity of Specimen. Agencies shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other agency official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or

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any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance in the permanent record book.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. [The temperature of the portal specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.] The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of a specimen is outside the range of 32.5°-37.7°C/90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual may alter or substitute the specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19)–(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the agency.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter in the permanent record book all information identifying the specimen. The collection site person shall sign the permanent record book next to the identifying information.

(22) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(23) A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(24) The collection site person shall complete the chain of custody form.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and custody form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(g) *Collection Control.* To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) *Transportation to Laboratories.* Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specially designed boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the

container, the collection site supervisor shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

2.3 Laboratory Personnel.

(a) Day-to-Day Management.

(1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology, or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in 2.4(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) Test Validation. The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) Day-to-Day Operations and Supervision of Analysts. The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) Training. The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) Files. Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.4 Laboratory Analysis Procedures.

(a) Security and Chain of Custody. (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

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(b) Receiving. (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the agency's chain of custody forms attached to the shipment shall be immediately reported to the agency and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) Short-Term Refrigerated Storage. Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) Specimen Processing. Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) Initial Test. (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	[1] 300
Phencyclidine	25
Amphetamines	1,000

[1] 25ng/ml if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(f) Confirmatory Test. (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

	Confirmatory test level (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates	
Morphine	* 300
Codeine	* 300
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(g) Reporting Results. (1) The laboratory shall report test results to the agency's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the agency, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory *shall report as negative* all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the agency but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means [for example, teleprinters, facsimile, or computer] in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain of custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports.

(6) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

(A) Number of specimens received; and

(B) Number of specimens reported out; and

(C) Number of specimens screened positive for:

Marijuana metabolites.
Cocaine metabolites.
Opiate metabolites.
Phencyclidine.
Amphetamines.

(ii) Confirmatory Testing:

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite.

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Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by DHHS or any Federal agency for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) Long Term Storage. Long-term frozen storage (-20 °C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an agency may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) Retesting Specimens. Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) Subcontracting. Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the agency. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in these Guidelines.

(k) Laboratory Facilities. (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) Inspections. The Secretary, any Federal agency utilizing the laboratory, or any organization performing laboratory certification on behalf of the Secretary shall reserve the right to inspect the laboratory at any time. Agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the award of a contract the agency shall carry out preaward inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(m) Documentation. The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by DHHS or by any Federal agency for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) Additional Requirements for Certified Laboratories.—(1) Procedure Manual. Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) Standards and Controls. Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in services; and expiration date.

(3) Instruments and Equipment. (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) Remedial Actions. There shall be written procedures for the actions to be taken when systems are out of accceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) Personnel Available To Testify at Proceedings. A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on positive urinalysis results reported by the laboratory.

2.5 Quality Assurance and Quality Control.

(a) General. Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) Laboratory Quality Control Requirements for Initial Tests. Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the

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testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory Quality Control Requirements for Confirmation Tests. Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Agency Blind Performance Test Procedures. (1) Agencies shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-Recognized certification program in accordance with these Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The Secretary shall investigate any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be make of the Secretary's investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the Secretary shall send the document to the agency contracting officer as a report of the unsatisfactory performance testing incident. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the laboratory shall submit all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operations of the laboratory. The Secretary has the option of revoking (3.13) or suspending (3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.6 Interim Certification Procedures.

During the interim certification period as determined under paragraph (c), agencies shall ensure laboratory competence by one of the following methods:

(a) Agencies may use agency or contract laboratories that have been certified for urinalysis testing by the Department of Defense; or

(b) Agencies may develop interim self certification procedures by establishing preaward inspections and performance testing plans approved by DHHS.

(c) The period during which these interim certification procedures will apply shall be determined by the Secretary. Upon notice by the Secretary that these interim certification procedures are no longer available, all Federal agencies subject to these Guidelines shall only use laboratories that have been certified in accordance with Subpart C of these Guidelines and all laboratories approved for interim certification under paragraphs (a) and (b) of this section shall become certified in accordance with Subpart C within 120 days of the date of this notice.

2.7 Reporting and Review of Results.

(a) Medical Review Officer Shall Review Results. An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to agency administrative officials.

(b) Medical Review Officer—Qualifications and Responsibilities. The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an agency or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the agency's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with these Guidelines.

(c) Positive Test Result. Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result

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with him or her. Following verification of a positive test result, the Medical Review Officer shall refer the case to the agency Employee Assistance Program and to the management official empowered to recommend or take administrative action.

(d) Verification for opiates; review for prescription medication. Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of illegal use of any opium, opiate, or opium derivative [e.g., morphine/codeine] listed in Schedule I or II of the Controlled Substances Act. [This requirement does not apply if the agency's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.]

(e) Reanalysis Authorized. Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified under these Guidelines.

(f) Result Consistent with Legal Drug Use. If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, he or she shall determine that the result is consistent with legal drug use and take no further action.

(g) Result Scientifically Insufficient. Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. [The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in 2.7(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with these Guidelines.] The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the agency. The Medical Review Officer shall report to the Secretary all negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

2.8 Protection of Employee Records.

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 552a. In addition, laboratory contracts shall require compliance with the patient access and confidentiality provisions of section 503 of Pub. L. 100–71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover both the agency's and the laboratory's records of employee urinalysis results. The contract and the Privacy Act System shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

2.9 Individual Access to Test and Laboratory Certification Results.

In accordance with section 503 of Pub. L. 100–71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

3.1 Introduction.

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

3.2 Goals and Objectives of Certification.

(a) Uses of Urine Drug Testing. Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated in 2.4 (e) and (f).

(b) Need to Set Standards; Inspections. Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus on-site inspection. Maintenance of certification requires participation in an every-other-month performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) Urine Drug Testing Applies Analytical Forensic Toxicology. The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, property documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

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3.3 General Certification Requirements.

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for certification under these standards.

3.4 Capability to Test for Five Classes of Drugs.

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: Marijuana, cocaine, opiates, amphetamines, and phencyclidine, using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (2.1(a) (1) and (2)) and the methods (2.4 (e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of using the methods specified. Certified laboratories must clearly inform non-Federal clients when procedures followed for those clients conform to the standards specified in these Guidelines.

3.5 Initial and Confirmatory Capability at Same Site.

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (2.4 (e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (2.1(a) (1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

3.6 Personnel.

Laboratory personnel shall meet the requirements specified in 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

3.7 Quality Assurance and Quality Control.

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs as specified in 2.5 of these Guidelines.

3.8 Security and Chain of Custody.

Laboratories shall meet the security and chain of custody requirements provided in 2.4(a).

3.9 One-Year Storage for Confirmed Positives.

All confirmed positive specimens shall be retained in accordance with the provisions of 2.4(h) of these Guidelines.

3.10 Documentation.

The laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in 2.4(m).

3.11 Reports.

The laboratory shall report test results in accordance with the specifications in 2.4(g).

3.12 Certification.

(a) General. The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified and laboratory that is certified by a DHHS-recognized certification program in accordance with these Guidelines.

(b) Criteria. In determining whether to certify a laboratory or to accept the certification of a DHHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality assurance/quality control program;

(4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

3.13 Revocation.

(a) General. The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by a DHHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) Factors to Consider. The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) Period and Terms. The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

3.14 Suspension.

(a) Criteria. Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by a DHHS-recognized certification program in accordance with these Guidelines.

(b) Period and Terms. The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

3.15 Notice; Opportunity for Review.

(a) Written Notice. When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service or registered or certified mail, return

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receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation, and

(3) The period of suspension or proposed revocation.

(b) Opportunity for Informal Review. The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date of mailing or service of the notice. The review shall be by a person or persons designated by the Secretary and shall be based on written submissions by the laboratory and the Department of Health and Human Services and, at the Secretary's discretion, may include an opportunity for an oral presentation. Formal rules of evidence and procedures applicable to proceedings in a court of law shall not apply. The decision of the reviewing official shall be final.

(c) Effective Date. A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) DHHS-Recognized Certification Program. The Secretary's responsibility under this section may be carried out by a DHHS-recognized certification program in accordance with these Guidelines.

3.16 Recertification.

Following the termination or expiration of any suspension or revocation, a laboratory may apply for recertification. Upon the submission of evidence satisfactory to the Secretary that the laboratory is in compliance with these Guidelines or any DHHS-recognized certification program in accordance with these Guidelines, and any other conditions imposed as part of the suspension or revocation, the Secretary may recertify the laboratory or accept the recertification of the laboratory by a DHHS-recognized certification program.

3.17 Performance Test Requirement for Certification.

(a) An Initial and Continuing Requirement. The performance testing program is a part of the initial evaluation of a laboratory seeking certification (both performance testing and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) Three Initial Cycles Required. Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for inspection and certification. These initial three cycles (and any required for recertification) can be compressed into a 3-month period (one per month).

(c) Six Challenges Per Year. After certification, laboratories shall be challenged every other month with one set of at least 10 specimens a total of six cycles per year.

(d) Laboratory Procedures Identical for Performance Test and Routine Employee Specimens. All procedures associated with the handling and testing of the performance test specimens by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) Blind Performance Test. Any certified laboratory shall be subject to blind performance testing (see 2.5(d)). Performance on blind test specimens shall be at the same level as for the open or non-blind performance testing.

(f) Reporting—Open Performance Test. The laboratory shall report results of open performance tests to the certifying organization in the same manner as specified in 2.4(g)(2) for routine laboratory specimens.

3.18 Performance Test Specimen Composition.

(a) Description of the Drugs. Performance test specimens shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analyte by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the specimen composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one specimen container, but generally no more than two drugs will be present in any one specimen in order to imitate the type of specimen which a laboratory normally encounters. For any particular performance testing cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of specimens.

(b) Concentrations. Performance test specimens shall be spiked with the drug classes and their metabolites which are required for certifications: marijuana, cocaine, opiates, amphetamines, and phencyclidine, with concentration levels set at least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated. Some performance test specimens may be identified for GC/MS assay only. Blanks shall contain less than 2 ng/ml of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

3.19 Evaluation of Peformance Testing.

(a) Initial Certification. (1) An applicant laboratory shall not report any false positive result during performance testing for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of performance testing required for initial certification, i.e., it must correctly identify and confirm 90 percent of the total drug challenges for each shipment. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total drug challenges which are ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger). Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

(b) Ongoing Testing of Certified Laboratories.—(1) False Positives and Procedures for Dealing With Them. No

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false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a class [e.g., codeine for morphine] are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positive:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error [clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurence of the particular error in the future and, if there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time fo final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for the day-to-day management of the laboratory's urine drug testing. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a retest sample must be corrected because the critieria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred. However, if the case is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action.

(vi) During the time required to resolve the error, the laboratory shall remain certified but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) Requirement to Identify and Confirm 90 Percent of Total Drug Challenges. In order to remain certified, laboratories must successfully complete six cycles of performance testing per year. Failure of a certified laboratory to maintain a grade of 90 percent on any required performance test cycle, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) Requirement to Quantitate 80 Percent of Total Drug Challenges at ±20 Percent or ±2 standard deviations. Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger).

(4) Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean. No quantitative values obtained by a certified laboratory may differ by more than 50 percent from the calculated reference group mean.

(5) Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug. For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2), (b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) Procedures When Requirements in Paragraphs (b)(2)–(b)(5) of this Section Are Not Met. If a certified laboratory fails to maintain a grade of 90 percent per test cycle after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3), (b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to successfully quantitate test results and how it failed to successfully quantitate. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) 80 Percent of Participating Laboratories Must Detect Drug. A laboratory's performance shall be evaluated for all samples for which drugs were spiked at concentrations above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) Participation Required. Failure to participate in a performance test or to participate satisfactorily may result in suspension or revocation of certification.

3.20 Inspections.

Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

3.21 Results of Inadequate Performance.

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in 3.13 and 3.14 of these Guidelines.

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